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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,397		Shizuo Akira	49862	1566

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EXAMINER
PROUTY, REBECCA E

ART UNIT	PAPER NUMBER
1652	15

DATE MAILED: 04/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/582,397	Applicant(s) Akira et al.
	Examiner Rebecca Prouty	Art Unit 1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 6, 2003*.

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *4, 5, and 9-12* is/are pending in the application.

4a) Of the above, claim(s) *4 and 5* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *9-12* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *13*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Claims 1-3 and 6-8 have been canceled. Claims 4, 5 and newly presented claims 9-12 are still at issue and are present for examination.

Applicants' arguments filed on 1-6-03, paper No. 14, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claims 4 and 5 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 11.

Applicant is required to comply with the sequence rules by inserting the sequence identification numbers of all sequences recited within the specification. It is particularly noted that Figure 4 shows sequences for there appears to be no corresponding sequence (i.e., hIKK-α and hIKK-β) in the sequence listing and for which the corresponding SEQ ID NO is not shown either in the figure itself nor in the corresponding Brief description thereof. See particularly 37 CFR 1.821(b-d).

Claims 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point

out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is indefinite as it depends from itself. It is assumed for purposes of further examination that this claim was intended to depend from Claim 10.

Claims 11 and 12 are indefinite in the recitation of "which acts on the immune response mechanism" and "which is a preventive or therapeutic agent for diseases involving the I-TRAF or the TRAF molecule" as it is unclear how these statements limit the compositions of Claim 10 (from which they depend).

Claims 9-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification as filed fails to provide support for the recitation of "more than 82% homologous to SEQ ID NO:2". This is a new matter rejection.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 9 is rejected under 35 U.S.C. 102(a) as being anticipated by Shimada et al.

Shimada et al. teach the cloning and expression of IKK-i having a sequence identical to SEQ ID NO:2

Applicants argue that Shimada et al. is not prior art as it was published after the filing date of applicants priority document. However, this is not persuasive because the priority document fails to provide support for the current claims. In particular, the priority document fails to provide support for the current claims to a genus of proteins "more than 82% homologous to SEQ ID NO:2".

Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Nagase et al. (EMBL entry D63485) as evidenced by Cao (US Patent 5,776,717).

Nagase et al. teach a human gene (KIAA0151) and encoded protein identical to the protein of SEQ ID NO:2. Cao evidence that the translation product of the human KIAA0151 gene is an IκB kinase and binds TRAF (see particularly column 6, lines 59-67).

Applicants appear to believe that Cao teach that the protein of SEQ ID NO:2 of Cao (named T2K) is the KIAA0151 gene. This is

clearly not the case. Cao teach that T2K and the human KIAA0151 gene product **are related proteins** which **both** exhibit the ability to specifically phosphorylate IκB serine 36 and to bind TRAF2 (see particularly column 6, lines 59-67). This is further confirmed by Examples 1 and 2 of Cao which specifically teach protocols for a T2K-IκBβ phosphorylation assay (example 1, column 7, lines 1-49) and a KIAA0151-IκBβ phosphorylation assay (example 2, column 7 line 50 - column 8, line 30) clearly showing that Cao tested both T2K and the KIAA0151 gene product for IκB kinase activity.

Applicants appear to further argue that neither Cao nor Nagase et al. teach that the KIAA0151 gene product binds I-TRAF. This is not persuasive as the KIAA0151 gene product is identical to SEQ ID NO:2 of the instant application. I-TRAF binding ability is an inherent property of this protein.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a),

the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimada et al. in view of Mercurio et al.

Shimada et al. is discussed above. They do not specifically disclose pharmaceutical compositions of the IKK kinase.

Mercurio et al. teach that IKK kinases activate transcription of NF-κB regulated genes which regulates the critical pathways of inflammation, proliferation and apotosis and thus drugs which modulate the activation and function of these kinases are likely to have therapeutic value in treatment of inflammatory, neurodegenerative diseases and cancer.

Therefore, it would have been obvious to one of ordinary skill in the art to combine the protein of Shimada et al. with an acceptable carrier in order to use it to treat such conditions.

Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagase et al. in view of Cao and Mercurio et al.

Nagase et al. and Cao are discussed above. They do not specifically disclose pharmaceutical compositions of the IKK kinase.

Mercurio et al. teach that IKK kinases activate transcription of NF-κB regulated genes which regulates the critical pathways of inflammation, proliferation and apotosis and thus drugs which modulate the activation and function of these kinases are likely to have therapeutic value in treatment of inflammatory, neurodegenerative diseases and cancer.

Therefore, it would have been obvious to one of ordinary skill in the art to combine the protein of Nagase et al. which is shown by Cao to be an IKK kinase with an acceptable carrier in order to use it to treat such conditions.

Applicants appear to rely on the same arguments discussed above to traverse the instant rejections. Thus the instant rejections are maintained for the reasons presented above.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D. whose telephone number is (703) 308-4000. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (703) 308-3804. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Rebecca Prouty
Primary Examiner
Art Unit 1652